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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,606	10/16/2001	Barry E. Rothenberg	24065-004CON	6347

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MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY and POPEO, P.C.
One Financial Center
Boston, MA 02111

EXAMINER

WILDER, CYNTHIA B

ART UNIT PAPER NUMBER

1637

DATE MAILED: 12/17/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,606

Applicant(s)

Rothenberg et al.

Examiner

Cynthia B Wilder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 30, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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DETAILED ACTION

1. This case has been transferred from Examiner Shar Hashemi to Examiner Cynthia Wilder. Any further correspondence should be directed to the Examiner's contact information recited at the end of this action.
2. The previous restriction requirement inadvertently failed to address the issue of separate restriction for the polymorphisms (mutations) recited in the claims. Therefore, while appreciative of Applicant's kind election in Paper No. 13, this new restriction is necessitated to address the polymorphisms.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-24, drawn to a method of determining mutation in exon 2 of an HFE nucleic acid, classified in class 435, subclass 6.
 - II. Claims 25-33, drawn to a method of determining a mutation in an intron of an HFE genomic DNA, classified in class 435, subclass 6.
 - III. Claims 34-38, drawn to a method of determining a mutation in an HFE polypeptide, classified in class 435, subclass 7.1.
 - IV. Claims 49-52, drawn to a nucleic acid molecule that encodes an HFE polypeptide and kit, classified in class 536, subclass 23.1.

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- V. Claim 53, drawn to a kit comprising oligonucleotide primers, classified in class 536, subclass 24.33.
- VI. Claim 54-56, drawn to a purified HFE polypeptide, classified in class 530, subclass 369.
- VII. Claims 57, drawn to a kit comprising antibodies that binds epitope of a mutant HFE polypeptide, classified in class 435, subclass 287.2.
- VIII. Claims 58, drawn to a kit comprising antibodies that binds epitope of a wild-type HFE polypeptide, classified in class 435, subclass 287.2.

Mutations and Sequence election

Groups I-VIII each contains claims with regard to a specific mutation (i.e. single nucleotide polymorphisms) of SEQ ID NO: 1, SEQ ID NO: 27 and SEQ ID NO: 2. Election of one specific mutation corresponding to either SEQ ID NO: 1 or SEQ ID NO: 27 or SEQ ID NO: 2 is required along with election of one of Groups I-VIII. The broad claims will be examined along with the single mutation which is elected. *For example, if Group I is elected, claims 1-24, Applicant must elect one of the mutations corresponding to SEQ ID NO: 1. If Group II is elected, claims 25-33, Applicant must elect one of the mutations corresponding to SEQ ID NO: 27, etc.*

In addition, Group I detailed above reads on a combination of patentably distinct SEQ ID NOS: Each of the sequences are patentably distinct because the sequences are structurally unrelated and further restriction is applied to Group I. If Group I is elected, Applicant must further elect a forward and reverse primer from SEQ ID NOS: 3,4 or 15, 16 (see MPEP 803.04). Applicant must

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specifically identify each of the corresponding SEQ ID NO:X, SEQ ID NO: Y for the sequence elected. The broad claims will be examined along with the specific single mutation and primers which are elected.

Applicant is advised that examination will be restricted to only the elected single mutation and SEQ ID NOS: and should not be construed as a species election.

Each of the single mutations is unrelated to each other mutation. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different inventions are unrelated because each mutation differs in structure and effect from each other specific mutation. Specifically, the chemical structure of the mutation is necessarily different from that of any other mutation because where, for example, in claims 5 and 6, the nucleic acid with a missense mutation at nucleotide 314 of SEQ ID NO:1 is chemically and structurally different from the mutation at nucleotide 277 of SEQ ID NO: 1; claims 7 and 8, or the mutation at 7055 of SEQ ID NO: 27 as depicted in claims 30 and 31. With regard to the different effect, the specification teaches that, for example, a mutation at nucleotide 314 of SEQ ID NO: 1, such as 314C leads to the expression of a mutant HFE product with the amino acid substitution I105T and participates in a hydrophobic pocket, whereas a mutation in intron 5, e.g., at nucleotide 7055 of SEQ ID NO: 27 is associated with hemochromatosis. Still further, the specification teaches that a mutation such as a amino acid substitution at residue 95 or proximal to residue 95 of SEQ ID

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NO: 2 affects salt bridge formation. As indicated above, these changes causes different effects as well as clearly resulting in different structures.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are drawn to a method of determining a nutation. Invention I is unrelated from Inventions II and III because it is drawn to a method of determining a mutation in exon 2 of an HFE nucleic acid. Invention II is unrelated from Inventions I and III because it is drawn to determining a mutation in an intron of an HFE genomic DNA. invention III is unrelated from Invention I and II because it is drawn to determining a mutation in an HFE polypeptide.

Invention IV, V, VII and VIII are drawn to a kit for detecting a mutations. Invention IV is unrelated from Inventions V, VII and VIII because is comprises nucleic acid encoding an HFE polypeptide and kit thereof. Invention V is unrelated from Inventions IV, VII and VIII because drawn to a kit comprising oligonucleotide primers wherein the first primer is 5' to exon 2 and the second primer is 3' to exon 2 of an HFE nucleic acid. Invention VII is unrelated to Inventions IV, V and VIII because it is drawn to a kit comprising an antibody that binds to an epitope of a mutant HFE polypeptide. Invention VIII is unrelated from Inventions IV, V and VII because it is drawn to a kit comprising antibody that binds to an epitope of a wild-type polypeptide.

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5. Inventions VI and I, II III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Group VI is drawn to a purified HFE polypeptide which may be used in assay technology, may serve as an HFE agonist or may function as a transferrin receptor antagonist whereas Groups I, II and III are drawn to a method of identifying a mutation that can be performed by methods of amplification or methods of hybridization or protein ligand binding assays.

6. Inventions I and Inventions IV, V, VII, VIII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the method of determining a mutation in exon 2 of an HFE nucleic acid as claimed in Invention I can be practiced by another materially different apparatus such as a kit containing restriction enzyme Bst4C I

7. Inventions II and Inventions IV, V, VII, VIII are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and

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materially different apparatus (MPEP § 806.05(g)). In this case, the method of determining a mutation in an intron of an HFE genomic DNA as claimed in Invention II can be practiced by another materially different apparatus such as a kit containing restriction enzyme Bst4C I.

8. Inventions III and IV, V, VII, VIII are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case, the method of determining a mutation in a n HFE polypeptide as claimed in Invention III can be practiced with another materially different apparatus such as kit containing restriction enzyme Bst4C I.

9. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for other Group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventor ship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

December 12, 2002


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

12/16/02